RULE

Department of Environmental Quality
Office of the Secretary
Legal Affairs Division

IAEA Transportation Safety Standards
(LAC 33:XV.455, 1501, 1502, 1503, 1504, 1505, 1506, 1507, 1508, 1509, 1510, 1511, 1512, 1513, 1514, 1515, 1516, 1517, 1518, 1519, 1520, and 1599) (RP048ft)

Editor's Note: A portion of this rule, which was published on pages 2102-2115 of the October 20, 2008, issue of the *Louisiana Register*, is being reprinted to correct a typographical error.

Under the authority of the Environmental Quality Act, R.S. 30:2001 et seq., and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., the secretary gives notice that rulemaking procedures have been initiated to amend the Radiation Protection regulations, LAC 33:XV.455, 1501, 1502, 1503, 1504, 1505, 1506, 1507, 1508, 1509, 1510, 1511, 1512, 1513, 1514, 1515, 1516, 1517, 1518, 1519, 1520, and 1599 (Log #RP048ft).

This proposed rule is identical to federal regulations found in 10 CFR Part 71, which are applicable in Louisiana. For more information regarding the federal requirement, contact the Regulation Development Section at (225) 219-3471 or Box 4302, Baton Rouge, LA 70821-4302. No fiscal or economic impact will result from the proposed rule. This rule will be promulgated in accordance with the procedures in R.S. 49:953(F)(3) and (4).

This rule will update the state regulations to be compatible with the changes in the federal regulations. The change in the state regulations is a category B (must do) requirement of the NRC agreement. The state radiation protection regulations in LAC 33:XV.Chapter 15 are being amended and reorganized to mirror the federal regulations; some entire sections and parts of some sections are being moved and renumbered. The federal "IAEA Transportation Safety Standards and Other Transportation Safety Amendments" requirements are in 10 CFR Part 71. The federal rule covers transportation of radioactive material on public routes of roadways, railways, and waterways, and by air. It includes the types of containers that can be used, radiation levels at the surface of the package, labeling of the containers, and markings on the vehicles used for transport. The basis and rationale for this rule are to be compatible with the federal regulations and maintain an adequate Agreement State program. This proposed rule meets an exception listed in R.S. 30:2019(D)(2) and R.S. 49:953(G)(3); therefore, no report regarding environmental/health benefits and social/economic costs is required.

Title 33
ENVIRONMENTAL QUALITY

Part XV. Radiation Protection

Chapter 15. Transportation of Radioactive Material

§1520. Quality Assurance

A. Quality Assurance Requirements

1. This Section describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this Section, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component in accordance with predetermined requirements. The licensee, certificate holder, and applicant for a CoC are responsible for the quality assurance requirements as they apply to design, fabrication, testing, and modification of packaging. Each licensee is responsible for the quality assurance provision that applies to its use of a packaging for the shipment of licensed material subject to the quality assurance requirements of this Section.

2. Each licensee, certificate holder, and applicant for a CoC shall establish, maintain, and execute a quality assurance program that satisfies each of the applicable criteria of this Section and that satisfies any specific provisions that are applicable to the licensee's activities, including procurement of packaging. The licensee, certificate holder, and applicant for a CoC shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

3. Before using any package for the shipment of licensed material subject to this Section, each licensee shall obtain U.S. NRC approval of its quality assurance program. Using an appropriate method listed in 10 CFR 71.1(a), each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this Section are applicable and how they will be satisfied, by submitting the description to the Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Washington, DC 20555.

4. A U.S. NRC approved quality assurance program that satisfies the applicable criteria of 10 CFR Part 71, Subpart H, 10 CFR Part 50, Appendix B, or 10 CFR Part 72, Subpart G, and that is established, maintained, and executed regarding transport packages, will be accepted as satisfying the requirements of Paragraph A.2 of this Section. Before first use, the licensee, certificate holder, and applicant for a CoC shall notify the U.S. NRC, in accordance with 10 CFR 71.1, of its intent to apply its previously-approved Subpart H, Appendix B, or Subpart G quality assurance program to transportation activities. The licensee, certificate holder, and applicant for a CoC shall identify the program by date of submittal to the U.S. NRC, Docket Number, and date of U.S. NRC approval.

5. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices, and

meeting the requirements of LAC 33:XV.547.B, is deemed to satisfy the requirements of LAC 33:XV.1507.B and Paragraph A.2 of this Section.

B. Quality Assurance Organization

1. The licensee (or anyone who designs, fabricates, assembles, and tests the package before the package approval is issued), certificate holder, and applicant for a CoC shall be responsible for the establishment and execution of the quality assurance program. The licensee, certificate holder, and applicant for a CoC may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. The delegatable activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

2. The quality assurance functions consist of assuring that an appropriate quality assurance program is established and effectively executed, and verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.

3. The person or organization performing quality assurance functions must be given sufficient authority and organizational freedom to:

a. identify problems with quality;

b. initiate, recommend, or provide solutions; and

c. verify implementation of solutions.

4. A person or organization performing quality assurance functions must report to a management level that assures that the required authority and organizational freedom, including sufficient independence from cost and schedule factors, when opposed to safety considerations, are provided.

5. Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location(s) where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that persons and organizations assigned the quality assurance functions have the required authority and organizational freedom.

6. Irrespective of the organizational structure, any individual assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this Section are being performed, must have direct access to the levels of management necessary to perform this function.

C. Quality Assurance Program

1. The licensee, certificate holder, and applicant for a CoC shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of this Section. The licensee, certificate holder, and applicant for a CoC shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee, certificate holder, and applicant for a CoC shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

2. The licensee, certificate holder, and applicant for a CoC, through a quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as

necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee, certificate holder, and applicant for a CoC shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee, certificate holder, and applicant for a CoC shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

3. The licensee, certificate holder, and applicant for a CoC shall base the requirements and procedures of the quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:

a. the impact of malfunction or failure of the item on safety;

b. the design and fabrication complexity or uniqueness of the item;

c. the need for special control of, and surveillance over, processes and equipment;

d. the degree to which functional compliance can be demonstrated by inspection or test; and

e. the quality history and degree of standardization of the item.

4. The licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.

D. Handling, Storage, and Shipping Control. The licensee, certificate holder, and applicant for a CoC shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as an inert gas atmosphere and specific moisture content and temperature levels, must be specified and provided.

E. Inspection, Test, and Operating Status

1. The licensee, certificate holder, and applicant for a CoC shall establish measures to indicate, by the use of markings such as stamps, tags, labels, or routing cards, or by other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary, to preclude inadvertent bypassing of the inspections and tests.

2. The licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

F. Nonconforming Materials, Parts, or Components. The licensee, certificate holder, and applicant for a CoC shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements in order to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification,

documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

G. Corrective Action. The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action is taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

H. Quality Assurance Records. The licensee, certificate holder, and applicant for a CoC shall maintain sufficient written records to describe the activities affecting quality. The records must include the instructions, procedures, and drawings required by 10 CFR 71.111 to prescribe quality assurance activities and must include closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include instructions or procedures that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee, certificate holder, and applicant for a CoC shall retain these records for three years beyond the date when the licensee, certificate holder, and applicant for a CoC last engaged in the activity for which the quality assurance program was developed. If any portion of the written procedures or instructions is superseded, the licensee, certificate holder, and applicant for a CoC shall retain the superseded material for three years after it is superseded.

I. Audits. The licensee, certificate holder, and applicant for a CoC shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Follow-up action, including re-audit of deficient areas, must be taken where indicated.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2104(B) and 2113.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, Legal Affairs Division, LR 34:2112 (October 2008), repromulgated LR 34:0000 (November 2008).